#04-7984
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Subject: Comments on FR Doc. 04-7984.

Walt.-

Here are my comments on FR Doc. 04-7984.

At this time many of there are many testing issues with saliva and hair that need resolution. Issuing guidance would be indicative that testing is ready to be performed with the standards HHS requires of urine testing. The problems with the testing need to be resolved prior to the implementation of the new matrices. All testing needs to be accounted for and meet the minimum expectations that we have placed of urine drug testing.

1. Hair color bias is not acceptable in the drug testing arena. If there is a known variation in results depending on the racial origin of the donor. The results from these samples is unacceptable. Is it necessary to have multiple cutoffs for each of the hair color types?

2. The requirement for collecting two samples (split of saliva and split of urine) when oral fluid id requested is not very reasonable. Why not wait to see it THC can be properly testing in saliva before making the decision to adopt it as a proper sample for drug testing. It would be best to just let people know that THC abuse is acceptable! Also, how are you going to handle the collection procedures, have a 10 part Custody and Control form with 4 seals?

3. Why would you have the laboratories perform microscopic evaluations, dye tests etc... of samples instead of making the collection sites and the collectors accountable for making a proper collection. If we begin to perform dye tests, half the men and women over fifty would never be able to get a job. Just because there are issues on the tampering of urine because the collection is not observed, we should not make all other matrices suffer the same fate. There should be little to no need for adulteration testing in hair or saliva at this time if the collection is done properly.

4. It is unrealistic to perform a microscopic evaluation, a dye test, screening procedures and multiple confirmations with a sample of 50 mg of hair and then have the expectation that there would be enough sample for a split. What should the laboratories due in the case of a poly-drug user - select which drug to test for or call the client to see which of the drug they prefer to test for? Call every multi-positive sample invalid for testing? Also, there is no way to accurately compare the A and B samples for a hair sample if the samples are both kept in the sealed containers. Even if you were able to see them there is no way to do a comparison without tampering with the b container.

5. The testing technology is not up to the requirements of the testing required for hair and even saliva. I do not know of anyone able to achieve a 0.02 pg/mg cutoff necessary for THC in hair on a daily basis. If all the conditions on the GC/MS/MS or LC/MS/MS are optimal it is achievable, but not on a high production laboratory.

6. Will the laboratory have to reject an incorrect sample? As an example, Hair is not recommended for post-accident or for-cause. An employee comes in for a post accident collection. The client/department has selected hair as their main choice for drug testing. The collector inadvertently collects a hair sample, which is not suitable for post-accident. Should the sample be considered acceptable and tested or should the laboratory cancel the test and ask for a proper sample to be collected? If the sample is tested, the results would not be relevant to the period of time in question. If the sample is re-collected there is no way to assure the sample would be collected in a timely manner.

7. Regarding the IITF's. These facilities would become laboratories within themselves. In theory they would have to send a percentage of the negative samples to the confirmatory laboratory. If this is the case there could be a conflict of interest if the confirmatory laboratory gets a result different from the screening

laboratory. Should the MRO get the results from both the laboratory and the IITF'S and make the final evaluation.

8. How are they expecting for smaller collection sites to absorb the cost of the training and inspections necessary to be able to do the collections. I can see the majority of the collections sites withdrawing from performing regulated collections due to the cost associated with the regulated collections.

9. There needs to be a systematic study of the relevance of cutoffs from one matrix to another. There is no way you can accurately state that the cutoffs for each matrix are equivalent to the other matrices.

10. How is it possible to consider doing POC and be able to place the quality control that has been required of current laboratories? Each sample(s) would need to be tested with a negative control a 25% below cutoff and a 25 percent above cutoff control. Anyone that has done POC testing knows that the kits are incapable of this high degree of differentiation. Even the current manufacturers do not acknowledge false negative results with samples that are not more than 150% above cutoff.

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